

### General

### Guideline Title

U.S. selected practice recommendations for contraceptive use, 2016.

### Bibliographic Source(s)

Centers for Disease Control and Prevention (CDC). U.S. selected practice recommendations for contraceptive use, 2016. MMWR Recomm Rep: Morb Mortal Wkly Rep. 2016 Jul 29;65(4):1-66. [353 references] PubMed

#### **Guideline Status**

This is the current release of the guideline.

This guideline updates a previous version: Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. U.S. selected practice recommendations for contraceptive use, 2013: adapted from the World Health Organization selected practice recommendations for contraceptive use, 2nd edition. MMWR Recomm Rep. 2013 Jun 21;62(RR-05):1-60.

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Recommendations

# Major Recommendations

Note from the Centers for Disease Control and Prevention (CDC) and the National Guideline Clearinghouse (NGC): This guidance will be updated as new evidence becomes available. Please check the CDC's Division of Reproductive Health Web site for any changes that have been made to the recommendations since this guideline was published.

This document updates CDC's 2013 *U.S. Selected Practice Recommendations for Contraceptive Use* (U. S. SPR), based review of the scientific evidence and consultation with national experts. Major updates include:

- Revised recommendations for starting regular contraception after the use of emergency contraceptive pills
- New recommendations for the use of medications to ease insertion of intrauterine devices

#### How to Use This Document

The recommendations in this report are intended to help health care providers address issues related to use of contraceptives, such as how to help a woman initiate use of a contraceptive method, which examinations and tests are needed before initiating use of a contraceptive method, what regular follow-up is needed, and how to address problems that often arise during use, including missed pills and side effects such as unscheduled bleeding. Each recommendation addresses what a woman or health care provider can do in specific situations. For situations in which certain groups of women might be medically ineligible to follow the recommendations, comments and reference to *U.S. Medical Eligibility Criteria for* 

Contraceptive Use (U.S. MEC) are provided. The full U.S. MEC recommendations and the evidence supporting those recommendations have been updated in 2016 and are summarized (see Appendix A in the original guideline document).

The information in this document is organized by contraceptive method, and the methods generally are presented in order of effectiveness, from highest to lowest. However, the recommendations are not intended to provide guidance on every aspect of provision and management of contraceptive method use. Instead, they incorporate the best available evidence to address specific issues regarding common, yet sometimes complex, clinical issues. Each contraceptive method section generally includes information about initiation of the method, regular follow-up, and management of problems with use (e.g., usage errors and side effects). Each section first provides the recommendation and then includes comments and a brief summary of the scientific evidence on which the recommendation is based. The level of evidence from the systematic reviews for each evidence summary are provided based on the U.S. Preventive Services Task Force system, which includes ratings for study design (see the "Rating Scheme for the Strength of the Evidence" field), and categorization of the evidence as direct or indirect for the specific review question.

Recommendations in this document are provided for permanent methods of contraception, such as vasectomy and female sterilization, as well as for reversible methods of contraception, including the copper-containing intrauterine device (Cu-IUD); levonorgestrel-releasing IUDs (LNG-IUDs); the etonogestrel implant; progestin-only injectables; progestin-only pills (POPs); combined hormonal contraceptive methods that contain both estrogen and a progestin, including combined oral contraceptives (COCs), a transdermal contraceptive patch, and a vaginal contraceptive ring; and the standard days method (SDM). Recommendations also are provided for emergency use of the Cu-IUD and emergency contraceptive pills (ECPs).

For each contraceptive method, recommendations are provided on the timing for initiation of the method and indications for when and for how long additional contraception, or a back-up method, is needed. Many of these recommendations include guidance that a woman can start a contraceptive method at any time during her menstrual cycle if it is reasonably certain that the woman is not pregnant. Guidance for health-care providers on how to be reasonably certain that a woman is not pregnant is provided.

For each contraceptive method, recommendations include the examinations and tests needed before initiation of the method. These recommendations apply to persons who are presumed to be healthy. Those with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. U.S. MEC might be useful in such circumstances. Most women need no or very few examinations or tests before initiating a contraceptive method although they might be needed to address other noncontraceptive health needs. Any additional screening needed for preventive health care can be performed at the time of contraception initiation, and initiation should not be delayed for test results. The classification system was developed by the World Health Organization (WHO) and adopted by CDC to categorize the applicability of the various examinations or tests before initiation of contraceptive methods (refer to the "Rating Scheme for the Strength of the Recommendations" field).

The classifications focus on the relation of the examinations or tests to safe initiation of a contraceptive method. They are not intended to address the appropriateness of these examinations or tests in other circumstances. For example, some of the examinations or tests that are not deemed necessary for safe and effective contraceptive use might be appropriate for good preventive health care or for diagnosing or assessing suspected medical conditions. Systematic reviews were conducted for several different types of examinations and tests to assess whether a screening test was associated with safe use of contraceptive methods. Because no single convention exists for screening panels for certain diseases, including diabetes, lipid disorders, and liver diseases, the search strategies included broad terms for the tests and diseases of interest.

Summary charts and clinical algorithms that summarize the guidance for the various contraceptive methods have been developed for many of the recommendations, including when to start using specific contraceptive methods (see Appendix B in the original guideline document), examinations and tests needed before initiating the various contraceptive methods (see Appendix C in the original guideline document), routine follow-up after initiating contraception (see Appendix D in the original guideline document), management of bleeding irregularities (see Appendix E in the original guideline document), and management of IUDs when users are found to have pelvic inflammatory disease (PID) (see Appendix F in the original guideline document). These summaries might be helpful to health care providers when managing family planning patients. Additional tools are available on the U.S. Selected Practice Recommendations (SPR) Web site

#### Contraceptive Method Choice

Many elements need to be considered individually by a woman, man, or couple when choosing the most appropriate contraceptive method. Some of these elements include safety, effectiveness, availability (including accessibility and affordability), and acceptability. Although most contraceptive methods are safe for use by most women, U.S. MEC provides recommendations on the safety of specific contraceptive methods for women with certain characteristics and medical conditions; a U.S. MEC summary (see Appendix A in the original guideline document) and the categories of medical eligibility criteria for contraceptive use (see Box 1 in the original guideline document) are provided.

Voluntary informed choice of contraceptive methods is an essential guiding principle, and contraceptive counseling, where applicable, might be an important contributor to the successful use of contraceptive methods.

Contraceptive method effectiveness is critically important in minimizing the risk for unintended pregnancy, particularly among women for whom an unintended pregnancy would pose additional health risks. The effectiveness of contraceptive methods depends both on the inherent effectiveness of the method itself and on how consistently and correctly it is used (see Figure 1 in the original guideline document). Both consistent and correct use can vary greatly with characteristics such as age, income, desire to prevent or delay pregnancy, and culture. Methods that depend on consistent and correct use by clients have a wide range of effectiveness between typical use (actual use, including incorrect or inconsistent use) and perfect use (correct and consistent use according to directions). IUDs and implants are considered long-acting, reversible contraception (LARC); these methods are highly effective because they do not depend on regular compliance from the user. LARC methods are appropriate for most women, including adolescents and nulliparous women. All women should be counseled about the full range and effectiveness of contraceptive options for which they are medically eligible so that they can identify the optimal method.

In choosing a method of contraception, dual protection from the simultaneous risk for human immunodeficiency virus (HIV) and other sexually transmitted diseases (STDs) also should be considered. Although hormonal contraceptives and IUDs are highly effective at preventing pregnancy, they do not protect against STDs, including HIV. Consistent and correct use of the male latex condom reduces the risk for HIV infection and other STDs, including chlamydial infection, gonococcal infection, and trichomoniasis. Although evidence is limited, use of female condoms can provide protection from acquisition and transmission of STDs. All patients, regardless of contraceptive choice, should be counseled about the use of condoms and the risk for STDs, including HIV infection. Additional information about prevention and treatment of STDs is available from the CDC Sexually Transmitted Diseases Treatment Guidelines.

Women, men, and couples have increasing numbers of safe and effective choices for contraceptive methods, including LARC methods such as IUDs and implants, to reduce the risk for unintended pregnancy. However, with these expanded options comes the need for evidence-based guidance to help health care providers offer quality family planning care to their patients, including assistance in choosing the most appropriate contraceptive method for individual circumstances and using that method correctly, consistently, and continuously to maximize effectiveness. Removing unnecessary barriers can help patients access and successfully use contraceptive methods. Several medical barriers to initiating and continuing contraceptive methods might exist, such as unnecessary screening examinations and tests before starting the method (e.g., a pelvic examination before initiation of COCs), inability to receive the contraceptive on the same day as the visit (e.g., waiting for test results that might not be needed or waiting until the woman's next menstrual cycle to start use), and difficulty obtaining continued contraceptive supplies (e.g., restrictions on number of pill packs dispensed at one time). Removing unnecessary steps, such as providing prophylactic antibiotics at the time of IUD insertion or requiring unnecessary follow-up procedures, also can help patients access and successfully use contraception.

#### How to Be Reasonably Certain That a Woman Is Not Pregnant

In most cases, a detailed history provides the most accurate assessment of pregnancy risk in a woman who is about to start using a contraceptive method. Several criteria for assessing pregnancy risk are listed in the recommendation that follows. These criteria are highly accurate (i.e., a negative predictive value of 99% to 100%) in ruling out pregnancy among women who are not pregnant. Therefore, CDC recommends that health care providers use these criteria to assess pregnancy status in a woman who is about to start using contraceptives (see box below). If a woman meets one of these criteria (and therefore the health care provider can be reasonably certain that she is not pregnant), a urine pregnancy test might be considered in addition to these criteria (based on clinical judgment), bearing in mind the limitations of the accuracy of pregnancy testing. If a woman does not meet any of these criteria, then the health care provider cannot be reasonably certain that she is not pregnant, even with a negative pregnancy test. Routine pregnancy testing for every woman is not necessary.

On the basis of clinical judgment, health care providers might consider the addition of a urine pregnancy test; however, they should be aware of the limitations, including accuracy of the test relative to the time of last sexual intercourse, recent delivery, or spontaneous or induced abortion. Routine pregnancy testing for every woman is not necessary. If a woman has had recent (i.e., within the last 5 days) unprotected sexual intercourse, consider offering emergency contraception (either a Cu-IUD or ECPs) if pregnancy is not desired.

Box. How to Be Reasonably Certain That a Woman Is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- Is  $\leq$ 7 days after the start of normal menses
- Has not had sexual intercourse since the start of last normal menses
- Has been correctly and consistently using a reliable method of contraception
- Is ≤7 days after spontaneous or induced abortion
- Is within 4 weeks postpartum
- Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and
   6 months postpartum

#### Intrauterine Contraception

Four IUDs are available in the United States, the copper-containing IUD and three levonorgestrel-releasing IUDs (containing a total of either 13.5 mg or 52 mg levonorgestrel). Fewer than 1 woman out of 100 becomes pregnant in the first year of using IUDs (with typical use). IUDs are long-acting, are reversible, and can be used by women of all ages, including adolescents, and by parous and nulliparous women. IUDs do not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Information about initiation of Cu-IUDs and LNG-IUDs, examinations and tests needed before initiation of a Cu-IUD or an LNG-IUD, and other issues regarding IUD contraception is available in the original guideline document.

#### **Implants**

The etonogestrel implant, a single rod with 68 mg of etonogestrel, is available in the United States. Fewer than 1 woman out of 100 becomes pregnant in the first year of use of the etonogestrel implant with typical use. The implant is long acting, is reversible, and can be used by women of all ages, including adolescents. The implant does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Information about initiation of implants, examinations and tests needed before implant insertion, and other issues regarding implant contraception is available in the original guideline document.

#### **Injectables**

Progestin-only injectable contraceptives (depo-medroxyprogesterone acetate [DMPA], 150 mg intramuscularly or 104 mg subcutaneously) are available in the United States; the only difference between these two formulations is the route of administration. Approximately 6 out of 100 women will become pregnant in the first year of use of DMPA with typical use. DMPA is reversible and can be used by women of all ages, including adolescents. DMPA does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Information about initiation of injectables, examinations and tests needed before initiation of an injectable, and other issues regarding injectable contraception is available in the original guideline document.

#### Combined Hormonal Contraceptives

Combined hormonal contraceptives contain both estrogen and a progestin and include 1) COCs (various formulations), 2) a transdermal contraceptive patch (which releases 150 µg of norelgestromin and 20 µg ethinyl estradiol daily), and 3) a vaginal contraceptive ring (which releases 120 µg etonogestrel and 15 µg ethinyl estradiol daily). Approximately 9 out of 100 women become pregnant in the first year of use with combined hormonal contraceptives with typical use. These methods are reversible and can be used by women of all ages. Combined hormonal contraceptives are generally used for 21 to 24 consecutive days, followed by 4 to 7 hormone-free days (either no use or placebo pills). These methods are sometimes used for an extended period with infrequent or no hormone-free days. Combined hormonal contraceptives do not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Information about initiation of combined hormonal contraceptives, examinations and tests needed before initiation of combined hormonal contraceptives, and other issues regarding combined hormonal contraceptives is available in the original guideline document.

### Progestin-Only Pills

POPs contain only a progestin and no estrogen and are available in the United States. Approximately 9 out of 100 women become pregnant in the first year of use with POPs with typical use. POPs are reversible and can be used by women of all ages. POPs do not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Information about initiation of POPs, examinations and tests needed before initiation of POPs, and other issues regarding POPs is available in the original guideline document.

#### Standard Days Method

SDM is a method based on fertility awareness; users must avoid unprotected sexual intercourse on days 8 to 19 of the menstrual cycle. Approximately 5 out of 100 women become pregnant in the first year of use with perfect (i.e., correct and consistent) use of SDM; effectiveness based on typical use is not available for this method but is expected to be lower than that for perfect use. SDM is reversible and can be used by

women of all ages. SDM does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Information about use of SDM among women with various durations of the menstrual cycle is available in the original guideline document.

### **Emergency Contraception**

Emergency contraception consists of methods that can be used by women after sexual intercourse to prevent pregnancy. Emergency contraception methods have varying ranges of effectiveness depending on the method and timing of administration. Four options are available in the United States: the Cu-IUD and three types of ECPs.

Information about types of emergency contraception, initiation of emergency contraception, advance provision of ECPs, and other issues regarding emergency contraception is available in the original guideline document.

#### Female Sterilization

Laparoscopic, abdominal, and hysteroscopic methods of female sterilization are available in the United States, and some of these procedures can be performed in an outpatient procedure or office setting. Fewer than 1 out of 100 women become pregnant in the first year after female sterilization. Because these methods are intended to be irreversible, all women should be appropriately counseled about the permanency of sterilization and the availability of highly effective, long-acting, reversible methods of contraception. Female sterilization does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Information about when female sterilization is reliable for contraception is available in the original guideline document.

#### Male Sterilization

Male sterilization, or vasectomy, is one of the few contraceptive methods available to men and can be performed in an outpatient procedure or office setting. Fewer than 1 woman out of 100 becomes pregnant in the first year after her male partner undergoes sterilization. Because male sterilization is intended to be irreversible, all men should be appropriately counseled about the permanency of sterilization and the availability of highly effective, long-acting, reversible methods of contraception for women. Male sterilization does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

Information about when male sterilization is reliable for contraception and other postprocedure recommendations are available in the original guideline document.

### When Women Can Stop Using Contraceptives

Contraceptive protection is still needed for women aged >44 years if the woman wants to avoid pregnancy.

### Clinical Algorithm(s)

The following clinical algorithms are provided in the original guideline document:

- Recommended actions after late or missed combined oral contraceptives (Figure 2)
- Recommended actions after delayed application or detachment with combined hormonal patch (Figure 3)
- Recommended actions after delayed insertion or reinsertion with combined vaginal ring (Figure 4)
- Recommended actions after vomiting or diarrhea while using combined oral contraceptives (Figure 5)
- Management of women with bleeding irregularities while using contraception (Appendix E)
- Management of intrauterine devices when users are found to have pelvic inflammatory disease (Appendix F)

# Scope

# Disease/Condition(s)

Unintended pregnancy

# Guideline Category Counseling Evaluation Management Prevention Risk Assessment Screening Treatment Clinical Specialty Family Practice Infectious Diseases Internal Medicine Obstetrics and Gynecology **Pediatrics** Pharmacology Preventive Medicine **Intended Users** Advanced Practice Nurses Health Care Providers Pharmacists Physician Assistants Physicians Public Health Departments Guideline Objective(s) • To provide recommendations for health care providers on the safe and effective use of contraceptive methods • To address provision of contraceptive methods and management of side effects and other problems with contraceptive method use, within the framework of removing unnecessary medical barriers to accessing and using contraception • To update the 2013 U.S. Selected Practice Recommendations for Contraceptive Use (U.S. SPR) with new evidence and input from

# **Target Population**

experts

All women of reproductive age (including adolescents) and their male partners residing in the United States

### **Interventions and Practices Considered**

- 1. Contraception methods
  - Intrauterine contraception, including copper-containing intrauterine device (Cu-IUD) and levonorgestrel-releasing IUD (LNG-IUD)
  - Etonogestrel implant
  - Depot medroxyprogesterone acetate (DMPA) injectable contraceptive
  - Combined hormonal contraceptives containing both estrogen and a progestin including combined oral contraceptives (COCs), transdermal contraceptive patch, vaginal contraceptive ring
  - Progestin-only pills (POPs)
  - Standard days method (based on fertility awareness)
  - Emergency contraception including Cu-IUD, ulipristal acetate (UPA) in a single dose, levonorgestrel in a single dose or as a split dose, combined estrogen and progestin in 2 doses (Yuzpe regimen)
  - Female sterilization (laparoscopic, abdominal, and hysteroscopic methods)
  - Male sterilization (vasectomy)

### 2. Initiation of contraception

- Ascertaining that woman is not pregnant
- Timing of IUD or implant insertion or initiation of other hormonal contraceptive methods
- Clinical examinations and laboratory tests needed before initiation of contraceptive methods (e.g., cervical examination and screening tests for sexually transmitted diseases [STDs])
- Provision of medications to ease IUD insertion (i.e., misoprostol [not recommended for routine use]; paracervical block with lidocaine)
- Provision of prophylactic antibiotics at the time of IUD insertion (not generally recommended)
- Advice on need for back-up contraception
- Special considerations for amenorrhea (not postpartum), postpartum (including after cesarean section), postpartum (breastfeeding and not breastfeeding), postabortion, switching from anther contraceptive method
- Counseling on potential changes in bleeding patterns and amenorrhea that occur with various contraceptive methods
- 3. Management of contraception and follow-up
  - Management of bleeding irregularities
  - Management of the IUD when a Cu-IUD or an LNG-IUD user is found to have pelvic inflammatory disease (PID) or when the user
    is found to be pregnant
  - Routine follow-up after IUD or implant insertion or after initiation of hormonal methods of contraception
  - Number of contraceptive pills to be provided at initial and return visits
  - Considerations for missed pills and vomiting or diarrhea while taking pills
  - Prevention and management of nausea and vomiting with emergency contraceptive pill use
  - Starting regular contraception after use of emergency contraception
  - Stopping contraceptive protection (age for discontinuation)

# Major Outcomes Considered

- Effectiveness of contraceptive methods
- Safety of contraceptive methods
- Satisfaction/side effects regarding contraceptive methods
- Unintended pregnancy rates

# Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Since publication of the 2013 *U.S. Selected Practice Recommendations for Contraceptive Use* (U.S. SPR), the Centers for Disease Control and Prevention (CDC) has monitored the literature for new evidence relevant to the recommendations through the World Health Organization (WHO)/CDC continuous identification of research evidence (CIRE) system. This system identifies new evidence as it is published and allows WHO and CDC to update systematic reviews and facilitate updates to recommendations as new evidence warrants. Automated searches are run in PubMed weekly, and the results are reviewed. Abstracts that meet specific criteria are added to the web-based CIRE system, which facilitates coordination and peer review of systematic reviews for both WHO and CDC.

CDC staff conducted independent systematic reviews for each of the topics being considered for U.S. SPR 2016. The purpose of these systematic reviews was to identify direct evidence related to the common clinical challenges associated with the recommendations. The full reviews have been published and contain the details of each review, including systematic review question, literature search protocol, inclusion and exclusion criteria, evidence tables, and quality assessment (see the "Availability of Companion Documents" field). CDC staff continued to monitor new evidence identified through the CIRE system during the preparation for the August 2015 meeting.

### Number of Source Documents

Five articles were added for the 2016 update, including 2 original randomized trials and 3 systematic reviews. Refer to the "Comments and Evidence Summary" sections of the guideline for the number of source documents for each recommendation.

### Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

### Rating Scheme for the Strength of the Evidence

The level of evidence from the systematic reviews for each evidence summary are provided based on the U.S. Preventive Services Task Force system (2001), which includes ratings for study design (I: randomized controlled trials; II-1: controlled trials without randomization; II-2: observational studies; and II-3: multiple time series or descriptive studies), ratings for internal validity (good, fair, or poor), and categorization of the evidence as direct or indirect for the specific review question.

### Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

# Description of the Methods Used to Analyze the Evidence

To review the scientific evidence for potential recommendations, the Centers for Disease Control and Prevention (CDC) staff conducted independent systematic reviews for each of the topics being considered. The purpose of these systematic reviews was to identify direct evidence related to the common clinical challenges associated with the recommendations. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed for reporting systematic reviews, and strength and quality of the evidence were assigned using the system of the U.S. Preventive Services Task Force. When direct evidence was limited or not available, indirect evidence (e.g., evidence on surrogate outcomes) and theoretical issues were considered and either added to direct evidence within a systematic review or separately compiled for presentation to the meeting participants. Completed systematic reviews were peer reviewed by two or three experts and then provided to participants before the expert meeting. Reviews are referenced throughout the original guideline document; the full reviews have been published and contain the details of each review, including systematic review question, literature search protocol, inclusion and exclusion criteria, evidence tables, and quality assessment (see the "Availability of Companion Documents" field). CDC staff continued to monitor new evidence identified through the continuous identification of research evidence (CIRE) system during the preparation for the August 2015 meeting.

### Methods Used to Formulate the Recommendations

Expert Consensus (Consensus Development Conference)

### Description of Methods Used to Formulate the Recommendations

In 2014, the Centers for Disease Control and Prevention (CDC) reviewed all of the existing recommendations in the 2013 U.S. Selected Practice Recommendations for Contraceptive Use (U.S. SPR) for new evidence identified by continuous identification of research evidence (CIRE) that had the potential to lead to a changed recommendation. During August 27-28, 2014, CDC held a meeting in Atlanta, Georgia, of 11 family planning experts and representatives from partner organizations to solicit their input on the scope of and process for updating both the 2010 U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC) and the 2013 U.S. SPR. The participants were experts in family planning and represented different provider types and organizations that represent health care providers. A list of participants is provided at the end of the original guideline document. The meeting related to topics to be addressed in the update of U.S. SPR based on new scientific evidence published since 2013 (identified though the CIRE system), topics addressed at a 2014 World Health Organization (WHO) meeting to update global guidance, and suggestions CDC received from providers for the addition of recommendations not included in the 2013 U.S. SPR (e.g., from provider feedback through e-mail, public inquiry, and questions received at conferences). CDC identified one topic to consider adding to the guidance: the use of medications to ease intrauterine device (IUD) insertion (evidence question: "Among women of reproductive age, does use of medications before IUD insertion improve the safety or effectiveness of the procedure [ease of insertion, need for adjunctive insertion measures, or insertion success] or affect patient outcomes [pain or side effects] compared with nonuse of these medications?"). CDC also identified one topic for which new evidence warranted a review of an existing recommendation: initiation of regular contraception after emergency contraceptive pills (evidence question: "Does ulipristal acetate for emergency contraception interact with regular use of hormonal contraception leading to decreased effectiveness of either contraceptive method?"). CDC determined that all other recommendations in the 2013 U.S. SPR were up to date and consistent with the current body of evidence for that recommendation.

During August 26–28, 2015, CDC held a meeting in Atlanta, Georgia, of 29 participants who were invited to provide their individual perspectives on the scientific evidence presented and to discuss potential recommendations that followed. Participants represented a wide range of expertise in family planning provision and research and included obstetrician/gynecologists, pediatricians, family physicians, nurse practitioners, epidemiologists, and others with research and clinical practice expertise in contraceptive safety, effectiveness, and management. Lists of participants and any potential conflicts of interest are provided at the end of the original guideline document. During the meeting, the evidence from the systematic review for each topic was presented, including direct evidence and any indirect evidence or theoretical concerns. Participants provided their perspectives on using the evidence to develop the recommendations that would meet the needs of U.S. health care providers. After the meeting, CDC determined the recommendations in this report, taking into consideration the perspectives provided by the meeting participants.

### Rating Scheme for the Strength of the Recommendations

The following classification system was developed by the World Health Organization (WHO) and adopted by the Centers for Disease Control and Prevention (CDC) to categorize the applicability of the various examinations or tests before initiation of contraceptive methods:

Class A: These tests and examinations are essential and mandatory in all circumstances for safe and effective use of the contraceptive method.

Class B: These tests and examinations contribute substantially to safe and effective use, although implementation can be considered within the public health context, service context, or both. The risk for not performing an examination or test should be balanced against the benefits of making the contraceptive method available.

Class C: These tests and examinations do not contribute substantially to safe and effective use of the contraceptive method.

# Cost Analysis

Women with thrombogenic mutations should not use combined hormonal contraceptives (U.S. Medical Eligibility Criteria) because of the increased risk for venous thromboembolism. However, studies have shown that universal screening for thrombogenic mutations before initiating combined oral contraceptives (COCs) is not cost-effective because of the rarity of the conditions and the high cost of screening.

### Method of Guideline Validation

### Description of Method of Guideline Validation

Feedback was received from four external reviewers, composed of health care providers and researchers who had not participated in the update meetings. These providers were asked to provide comments on the accuracy, feasibility, and clarity of the recommendations. Areas of research that need additional investigation also were considered during the meeting.

# **Evidence Supporting the Recommendations**

### Type of Evidence Supporting the Recommendations

The recommendations are based on the World Health Organization selected practice recommendations for contraceptive use, 2016, and the results from various systematic reviews (see the "Availability of Companion Documents" field). Refer to the "Comments and Evidence Summary" sections of the original guideline document for types and grades of evidence for specific recommendations.

# Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

- · Medically appropriate contraception assessment, counseling, and approach for individual circumstances
- Prevention of unintended pregnancy

Refer to the "Comments and Evidence Summary" sections in the original guideline document for commentary on specific benefits of individual recommendations.

### Potential Harms

- Unscheduled spotting or light bleeding or heavy or prolonged menstrual bleeding, especially during the first 3 to 6 months of use, are
  common with intrauterine devices (IUDs). Bleeding irregularities, including amenorrhea, commonly occur with implants, injectables, and
  other hormonal contraceptive methods.
- Risks for spontaneous abortion, preterm delivery, and infection are substantial if the IUD is left in place during pregnancy. Theoretically, the fetus might be affected by hormonal exposure from a levonorgestrel-releasing IUD (LNG-IUD); however, whether this exposure increases the risk for fetal abnormalities is unknown. A systematic review identified nine studies suggesting that women who did not remove their IUDs during pregnancy were at greater risk for adverse pregnancy outcomes (including spontaneous abortion, septic abortion, preterm delivery, and chorioamnionitis) compared with women who had their IUDs removed or who did not have an IUD. Copper-containing IUD (Cu-IUD) removal decreased risks but not to the baseline risk for pregnancies without an IUD. One case series examined LNG-IUDs. When they were not removed, eight in 10 pregnancies ended in spontaneous abortions.
- Theoretically, IUD insertion could induce bacterial spread and lead to complications such as pelvic inflammatory disease (PID) or infective endocarditis. A meta-analysis was conducted of randomized controlled trials examining antibiotic prophylaxis versus placebo or no treatment for IUD insertion. Use of prophylaxis reduced the frequency of unscheduled return visits but did not significantly reduce the incidence of PID or premature IUD discontinuation. Although the risk for PID was higher within the first 20 days after insertion, the incidence of PID was low among all women who had IUDs inserted. In addition, the American Heart Association recommends that the use of prophylactic antibiotics solely to prevent infective endocarditis is not needed for genitourinary procedures. Studies have not demonstrated a conclusive link between genitourinary procedures and infective endocarditis or a preventive benefit of prophylactic antibiotics during such procedures.
- Although hormonal contraceptives can have some adverse effects on glucose metabolism in healthy and diabetic women, the overall clinical
  effect is minimal.
- Women taking combined estrogen and progestin emergency contraception pills (ECPs) are more likely to experience nausea and vomiting
  than those who take levonorgestrel or ulipristal acetate (UPA) ECPs.

- Health-care providers should consider the risks for becoming pregnant in a woman of advanced reproductive age, as well as any risks of
  continuing contraception until menopause. Pregnancies among women of advanced reproductive age are at higher risk for maternal
  complications, such as hemorrhage, venous thromboembolism, and death, and fetal complications, such as spontaneous abortion, stillbirth,
  and congenital anomalies. Risks associated with continuing contraception, in particular risks for acute cardiovascular events (venous
  thromboembolism, myocardial infarction, or stroke) or breast cancer, also are important to consider.
- Figure 1 in the original guideline document shows the unintended pregnancy rate (within first year of typical use) for individual contraceptive methods.
- The U.S. Medical Eligibility Criteria for Contraceptive Use, 2016 (U.S. MEC) focuses on who can safely use specific methods of
  contraception and provides recommendations on safe use of contraceptive methods for women with various medical conditions and other
  characteristics (e.g., hypertension and diabetes) and characteristics (e.g., age, parity, and smoking status). See Appendix A in the original
  guideline document for a summary chart of the U.S. MEC.
- Evidence for misoprostol from two systematic reviews, including a total of 10 randomized controlled trials, suggests that misoprostol does
  not improve provider ease of insertion, reduce the need for adjunctive insertion measures, improve insertion and might increase patient pain
  and side effects.
- For methods requiring a visit to a health care provider, such as DMPA, implants, and IUDs, starting the method at the time of UPA use may be considered; the risk that the regular contraceptive method might decrease the effectiveness of UPA must be weighed against the risk of not starting a regular hormonal contraceptive method.

Refer to the "Comments and Evidence Summary" sections in the original guideline document for commentary on specific risks of individual recommendations.

### Contraindications

### Contraindications

Data regarding the overall safety of tranexamic acid are limited; a Food and Drug Administration (FDA) warning states that tranexamic acid is contraindicated in women with active thromboembolic disease or with a history or intrinsic risk for thromboesis or thromboembolism.

Refer to the "Comments and Evidence Summary" and "Special Considerations" sections in the original guideline document for additional information on interventions that are inappropriate for specific populations.

# **Qualifying Statements**

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- These recommendations are meant to serve as a source of clinical guidance for health care providers; health care providers should always
  consider the individual clinical circumstances of each person seeking family planning services. This report is not intended to be a substitute
  for professional medical advice for individual patients, who should seek advice from their health care providers when considering family
  planning options.
- Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.
- References to non-Centers for Disease Control and Prevention (CDC) sites on the Internet are provided as a service to MMWR readers
  and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human
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  publication.
- This document will not include any discussion of the unlabeled use of a product or a product under investigational use, with the exception that some of the recommendations in this document might be inconsistent with package labeling.

# Implementation of the Guideline

### Description of Implementation Strategy

The Centers for Disease Control and Prevention (CDC) is committed to working with partners at the federal, national, and local levels to disseminate, implement, and evaluate *U.S. Selected Practice Recommendations for Contraceptive Use 2016* (U.S. SPR) recommendations so that the information reaches health care providers. Strategies for dissemination and implementation include collaborating with other federal agencies and professional and service organizations to widely distribute the recommendations through presentations, electronic distribution, newsletters, and other publications; development of provider tools and job aids to assist providers in implementing the new recommendations; and training activities for students, as well as for continuing education. CDC conducts surveys of family planning health care providers to assess attitudes and practices related to contraceptive use. Results from these surveys will assist CDC in evaluating the impact of these recommendations on the provision of contraceptives in the United States. Finally, CDC will continually monitor new scientific evidence and will update these recommendations as warranted by new evidence. Updates to the recommendations, as well as provider tools and other resources, are available on the CDC U.S. SPR

Web site
Implementation Tools
Clinical Algorithm
Mobile Device Resources
Patient Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staff Training/Competency Material

Staying Healthy

Resources

### **IOM Domain**

Effectiveness

Patient-centeredness

Safety

Timeliness

# Identifying Information and Availability

Bibliographic Source(s)

Centers for Disease Control and Prevention (CDC). U.S. selected practice recommendations for contraceptive use, 2016. MMWR Recomm Rep: Morb Mortal Wkly Rep. 2016 Jul 29;65(4):1-66. [353 references] PubMed

### Adaptation

Not applicable: The guideline is not adapted from another source.

### Date Released

2016 Jul 29

### Guideline Developer(s)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

### Source(s) of Funding

United States Government

The Centers for Disease Control and Prevention (CDC) does not accept commercial support.

### Guideline Committee

Centers for Disease Control and Prevention (CDC) Guideline Development Group for U.S. Medical Eligibility Criteria for Contraceptive Use and U.S. Selected Practice Recommendations for Contraceptive Use

### Composition of Group That Authored the Guideline

Guideline Development Group Members: Kathryn M. Curtis, PhD, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, Georgia; Tara C. Jatlaoui, MD, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, Georgia; Naomi K. Tepper, MD, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, Georgia; Lauren B. Zapata, PhD, MD, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, Georgia; Leah G. Horton, MSPH, MD, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, Georgia; Denise J. Jamieson, MD, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, Georgia; Maura K. Whiteman, PhD, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, Georgia

### Financial Disclosures/Conflicts of Interest

#### Disclosure of Relationship

The Centers for Disease Control and Prevention (CDC), its planners, and its content experts wish to disclose they have no financial interest or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Planners have reviewed content to ensure there is no bias. This document will not include any discussion of the unlabeled use of a product or a product under investigational use, with the exception that some of the recommendations in this document might be inconsistent with package labeling.

### Handling Conflicts of Interest

To promote transparency, all participants were asked to disclose any potential conflicts of interest to CDC prior to the expert meeting and to report any potential conflicts of interest during the introductory portion of the expert meeting. All potential conflicts of interest are listed in the original guideline document. No participants were excluded from discussion based on potential conflicts of interest. CDC staff who ultimately decided and developed these recommendations have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters relevant to these recommendations.

### **Guideline Status**

This is the current release of the guideline.

Guideline Availability

This guideline updates a previous version: Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. U.S. selected practice recommendations for contraceptive use, 2013: adapted from the World Health Organization selected practice recommendations for contraceptive use, 2nd edition. MMWR Recomm Rep. 2013 Jun 21;62(RR-05):1-60.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Available from the Centers for Disease Control and Prevention (CDC) Web site
Availability of Companion Documents
The following are available:
<ul> <li>Salcedo J, Rodriguez MI, Curtis KM, Kapp N. When can a woman resume or initiate contraception after taking emergency contraceptive pills? A systematic review. Contraception 2013 May;87(5):602-4. Available to subscribers from the Contraception Web site</li> <li>Zapata LB, Jatlaoui TC, Marchbanks PA, Curtis KM. Medications to ease intrauterine device insertion: a systematic review. Contraception 2016 Dec;94(6):739-59. Available to subscribers from the Contraception Web site</li> <li>Lopez LM, Bernholc A, Zeng Y, et al. Interventions for pain with intrauterine device insertion. Cochrane Database Syst Rev 2015;7:CD007373. Available from the Cochrane Library Web site</li> </ul>
In addition, summary charts and clinical algorithms that summarize the guidance for the various contraceptive methods are available in the original guideline document, including a Summary Chart of <i>U.S. Medical Eligibility Criteria for Contraceptive Use, 2016</i> (Appendix A), when to start using specific contraceptive methods (Appendix B), examinations and tests needed before initiating the various contraceptive methods (Appendix C), routine follow-up after initiating contraception (Appendix D), management of bleeding irregularities (Appendix E), and management of intrauterine devices (IUDs) when users are found to have pelvic inflammatory disease (PID) (Appendix F).
A continuing education examination is available from the Centers for Disease Control and Prevention (CDC) Web site
Additional tools, including an app, are available on the CDC Web site
Patient Resources
A Birth Control Methods Fact Sheet is available from the Womenshealth.gov Web site
Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and

### **NGC Status**

This NGC summary was completed by ECRI Institute on April 18, 2014. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on January 18, 2017.

answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or

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